EPMedSystems

510(k) Summary

Summary preparation date: 03/13/07

APR 11 2007

1.0 Device Trade Name

Device Trade Name	Device Classification
EP-WorkMate®	Programmable Diagnostic Computer

2.0 Establishment Address and Registration

EP MedSystems Inc.
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 USA

Larry Picciano
Telephone: 856-753-8533, x221
Fax: 856-753-8544
E-mail: lpicciano@epmedsystems.com

US Food and Drug Administration Establishment Registration No.: 2248049

3.0 Device Classification

Programmable diagnostic computers have been classified as Class II, 74 DQK. No performance standards have been established under CFR 21 Part 870.1425 or Section 514 of the Food, Drug, and Cosmetic Act for programmable diagnostic computers.

4.0 *Predicate Devices / Technology

Product Description	510 (k) No.	Date
EP-WorkMate®	K994011	03/23/00

* This application describes a modification to the EP-WorkMate® called NurseMate™ with Physio Module.

5.0 Labeling and Intended Use

The following labeling is contained within **Appendix 4.**

5.1 Proposed Product Labeling
5.2 Proposed Marketing Literature
5.3 Proposed Instructions for Use Manual (See chapter 10)

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5.4 **Intended Use**

The EP-WorkMate® is intended to be used with an EP-3 [K935590] or EP-4 [K0401442] stimulator for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachy-arrhythmias measurements of electrical conduction.

6.0 Indications for Use

Indications for Use Statement

EP-WorkMate® is indicated for use during clinical electrophysiology procedures.

7.0 Device Description

7.1 **Background description of EP-WorkMate® with NurseMate™:**

Cardiac EP studies are diagnostic tests that enable physicians to look at electrical signals from within the heart in detail to determine if an abnormality (arrhythmia) exists. The cardiac EP laboratory is typically staffed with one or more physicians, nurses, and technologists thus making the lab a busy and sometimes crowded workspace. A physician directs the EP study and the operation of the EP-WorkMate® [K994011] system; some physicians operate the system, others direct a member of the clinical staff on the system operation. The EP-WorkMate® system is illustrated in **Figure 1**. Under the direction of a physician, the cardiac stimulator delivers diagnostic stimuli to the heart through the EP catheter(s). The heart's electrical response to the diagnostic signals is returned through the catheter(s) to the amplifier/signal conditioning unit (Amp/SCU). The amplified and conditioned signals are displayed as waveforms and tabular EP data on the EP-WorkMate® real-time display monitor for diagnosis by the physician. A physician may also choose to record/store the signals using the EP-WorkMate®.

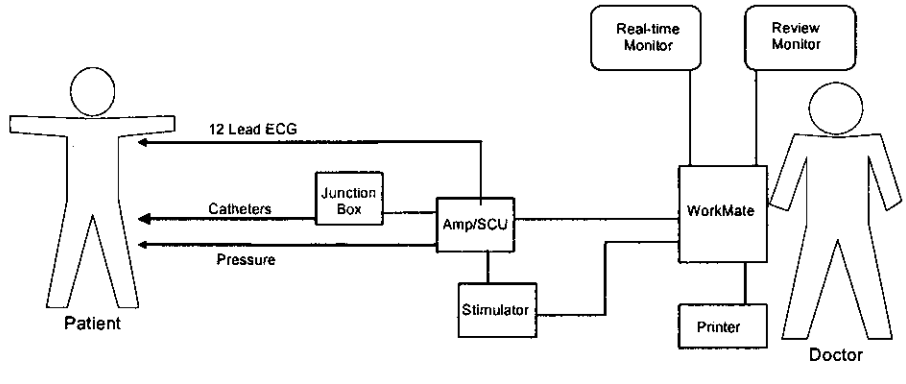

Figure 1: EP-WorkMate® System Block Diagram

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7.2 NurseMate™ [K063113] is a modification to the EP-WorkMate® computer that is offered as an option to customers under the name NurseMate™. NurseMate™ is a PC (Personal Computer) workstation that is connected to the EP-WorkMate® system for real-time patient charting, physiologic monitoring, and data analysis during electrophysiology (EP) studies. The interconnection of NurseMate™ to EP-WorkMate® is illustrated in **Figure 2**. Expanding the EP-WorkMate® system with the optional NurseMate™ creates an additional workstation for a member of the EP team such as a nurse. The additional workstation reduces crowding at the main EP-WorkMate® station and eases workflow congestion in the busy cardiac EP laboratory. Using NurseMate™ an EP lab staff member can perform patient charting (e.g., event titles, medications, and comments) and monitor physiologic data from the Amp/SCU including heart rate (HR) and blood pressure (BP) on their own display separate from the physician who is controlling the EP study using EP-WorkMate® workstation. **Figure 3** illustrates NurseMate's™ graphical user interface (GUI) displaying HR and BP.

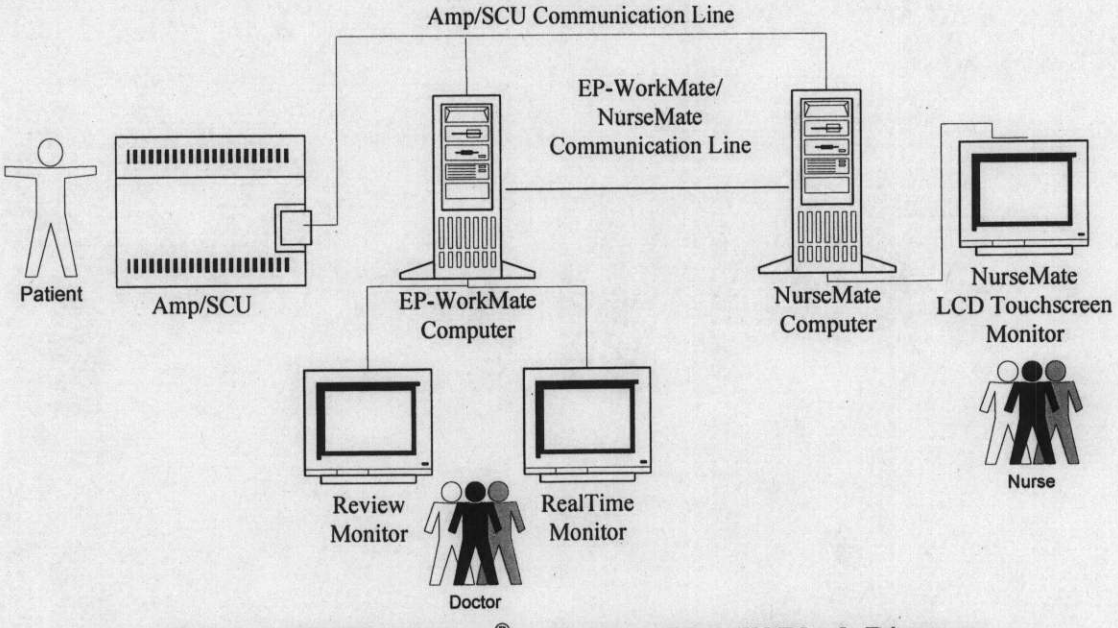

Figure 2: EP-WorkMate® with NurseMate™ Block Diagram

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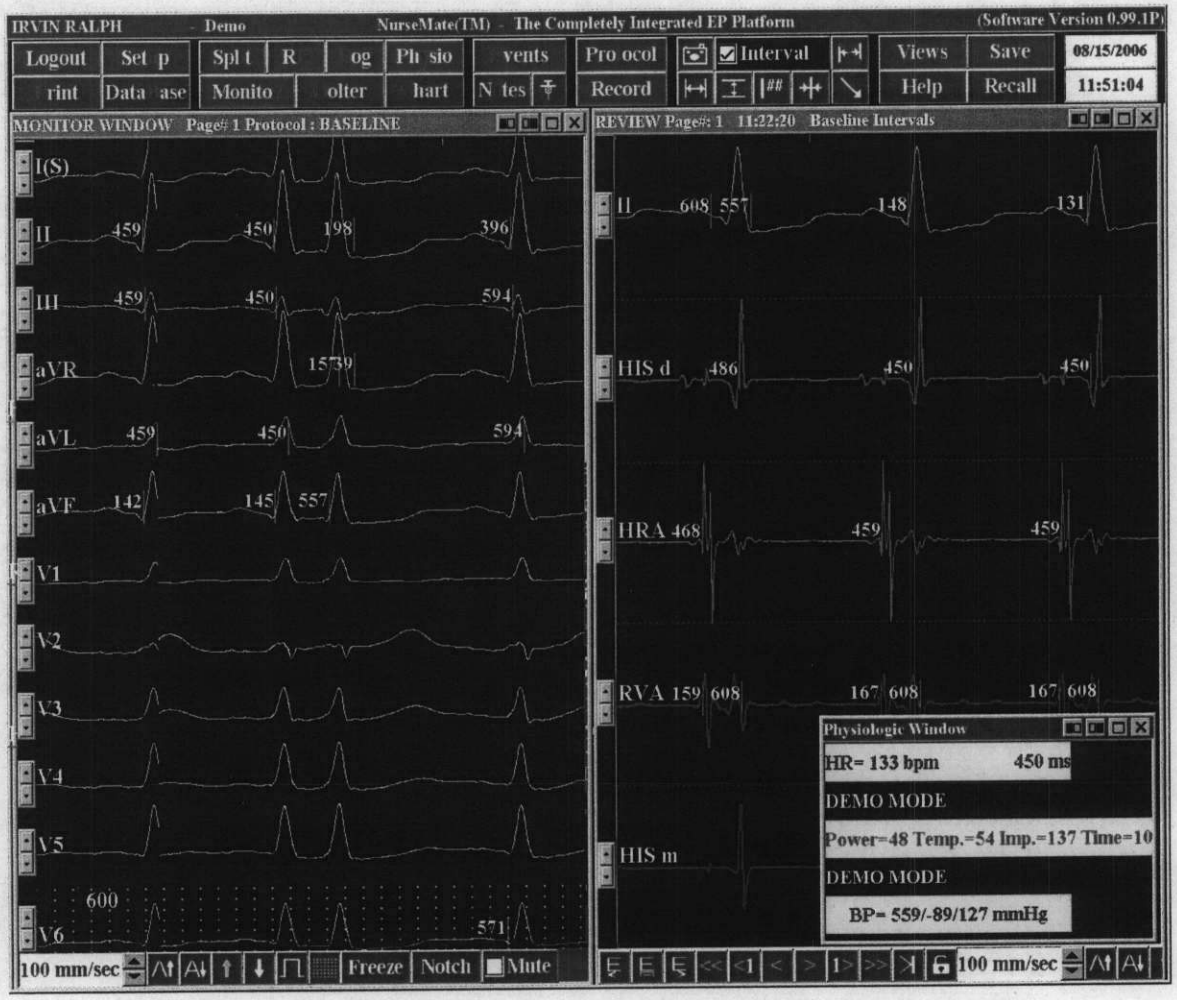

Figure 3: NurseMate™ Graphical User Interface with Physiologic Data

7.3 **General description of NurseMate™ with Physio Module:** This application describes a modification to the EP-WorkMate® with NurseMate™ system that will be offered as an option to customers under the name NurseMate™ with Physio Module. NurseMate™ with Physio Module is a simple modification to EP-WorkMate® with NurseMate™ that allows data from an OEM (Original Equipment Manufacturer) physiologic monitoring device (connected to NurseMate™) to be logged into the current EP-WorkMate® database. The benefit of this product is reduced manual data entry and improved data management. NurseMate™ with Physio Module PC workstation is connected to the EP-WorkMate® system; it may also be connected to an OEM physiologic monitor. Interconnection of NurseMate™ with Physio Module to a physiologic monitor is accomplished using a serial data cable; this is illustrated in **Figure 4**. Use of an OEM physiologic monitoring device is not affected in any way by integration with NurseMate™; users follow the monitor's IFU and operate the device in accordance with its intended use.

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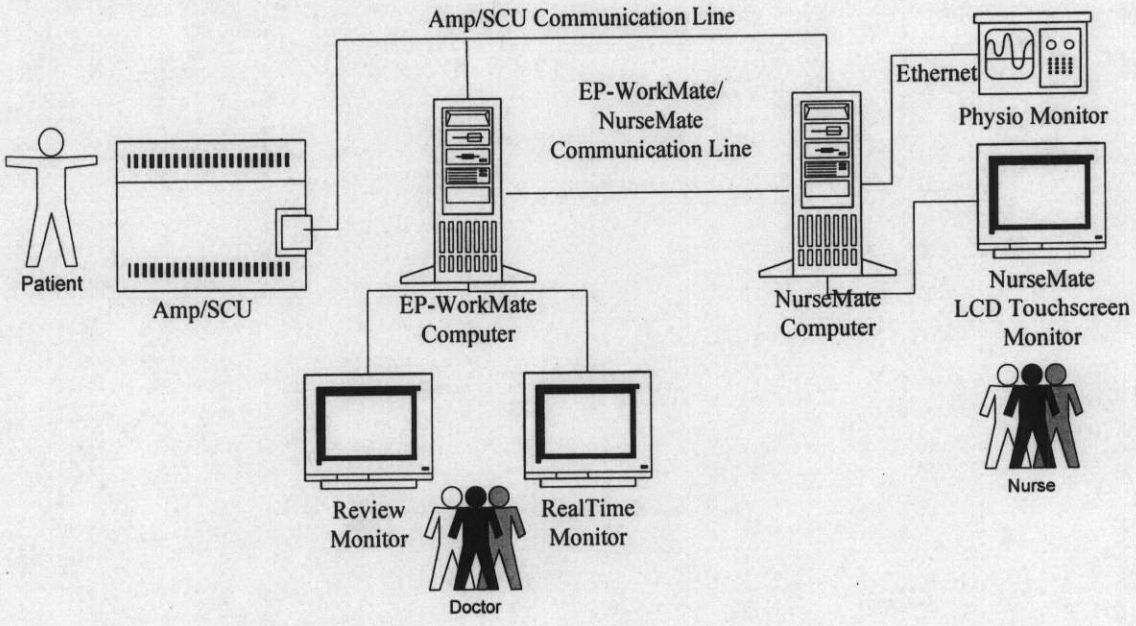

Figure 4: EP-WorkMate® with NurseMate™ with Physio Module Block Diagram

7.4 The intent of this submission is to provide premarket notification that the company shall offer the ability to log data from OEM monitors in general. Hence, EPMedSystems employs design controls, verification and validation processes in the integration of physiologic monitors with NurseMate™ with Physio Module. Any monitor intended for integration and sale in the US must have, at a minimum, FDA market clearance. As of this writing, the company has completed one device-specific physiologic monitor interface; this interface is for the Advisor® Vital Signs Monitor [K010770] made by Smiths Medical PM, Inc., Patient Monitoring and Ventilation, N7 W22025 Johnson Drive, Waukesha, Wisconsin 53186. The Advisor® is cleared for market under its own 510(k) [K010770]. The Advisor®'s monitoring modalities recorded by NurseMate™ include: temperature (TEMP), respiration rate (RESP), oximetry (SpO_2), noninvasive blood pressure (NIBP) and endtidal CO_2 ($EtCO_2$).

7.5 **NurseMate™ with Physio Module software description:** The NurseMate™ with Physio Module software is simply a modified version of the EP-WorkMate® with NurseMate™ application software. The EP-WorkMate® with NurseMate™ software was modified using the same Microsoft Visual C++ 6.0 Integrated Development Environment (with Visual Studio Service Pack 6.0) within which it was developed. The NurseMate™ with Physio Module for EP-WorkMate® program code was added into the WorkMate® with NurseMate™ C++ program code; hence, the software applications are highly similar. It is important to note that NurseMate™ with Physio Module does not control the patient monitor and

it does not control cardiac stimulation. A list comprising a functional software comparison between EP-WorkMate® and NurseMate™ with Physio Module is presented in **Table 1**.

7.6 **NurseMate™ with Physio Module hardware description:** NurseMate™ with Physio Module electronics hardware is identical to that of the original NurseMate™ system; these were designed and built using similar PC technology employed in the EP-WorkMate®. NurseMate™ with Physio Module comprises a: PC, touch screen LCD monitor, Central Processing Unit (CPU), mouse, keyboard, an equipment cart and optional physiologic monitor mounting hardware. The CPU is an off-the-shelf Pentium® microprocessor based personal computer running Microsoft Windows® Operating System (OS), with on board Random Access Memory (RAM), a Hard Disk Drive (HDD), a Read/Writable (R/W) Compact Disk (CD), multiple Universal Serial Bus (USB) ports, and a Network Interface Controller (NIC). The NurseMate™ with Physio Module station is identical to the original NurseMate™ station. Compared to EP-WorkMate®, NurseMate™ has a smaller, more movable form factor; it has a single display monitor and a smaller footprint cart with castors. **Figure 5** illustrates the NurseMate™ with Physio Module station form factor including the optional physiologic monitor and mounting hardware.

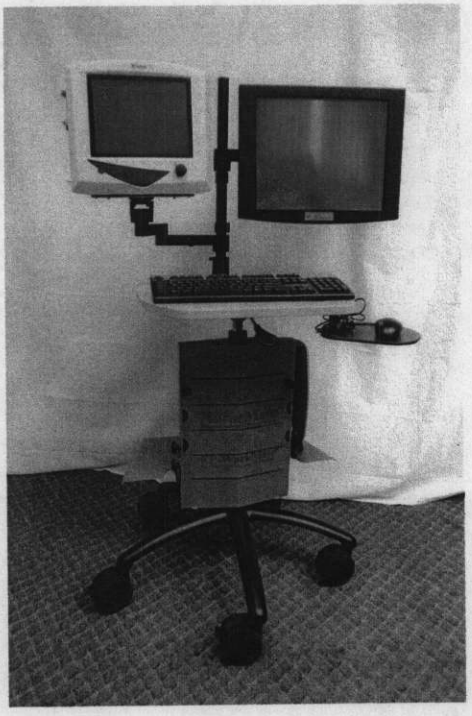

Figure 5: NurseMate™ with Physio Module Work Station

7.7 **EP-WorkMate® to NurseMate™ with Physio Module connections:** To use NurseMate™ with Physio Module as intended, three basic interconnections are required:

7.7.1 **EP-WorkMate® (PC) to NurseMate™ (PC) connection:** The first interconnection between the two computers illustrated in **Figure 6** is required for the client-server operation. The EP-WorkMate® acts as the server and the NurseMate™ with Physio Module acts as the client via handshaking signals. The client is passive except in that NurseMate™ with Physio Module can issue commands to the WorkMate® to start/stop data recording. The hardware interconnection between the computers is comprised of off-the-shelf category five (CAT 5) network cabling; the connections are terminated with standard data communication connectors (RJ-45). LAN connectivity is established using standard networking software protocol, Telecommunications Protocol/Internet Protocol (TCP/IP).

7.7.2 **NurseMate™ (PC) to EP-WorkMate® (Amp/SCU) connection:** The second interconnection between the NurseMate™ with Physio Module computer and the EP-WorkMate® amplifier/signal conditioning unit (Amp/SCU) uses the same hardware as a LAN connection. Communication is accomplished using a common software protocol known as Packet Driver which is similar to TCP/IP. This connection enables the NurseMate™ with Physio Module user to independently configure and view real time patient EP waveforms from the Amp/SCU during an EP study.

7.7.3 **NurseMate™ (PC) to OEM Physiologic Monitor:** The third interconnection is between the NurseMate™ with Physio Module computer and the OEM physiologic monitor; this uses a standard serial cable. The NurseMate™ (PC) to OEM physiologic monitor interconnection is terminated with a standard 9 pin connector (DB-9) at the OEM monitor and a Universal Serial Bus (USB) connector at the NurseMate™ PC. Transmission of the data from the OEM physiologic monitor to the NurseMate™ is accomplished via basic serial data communications protocol.

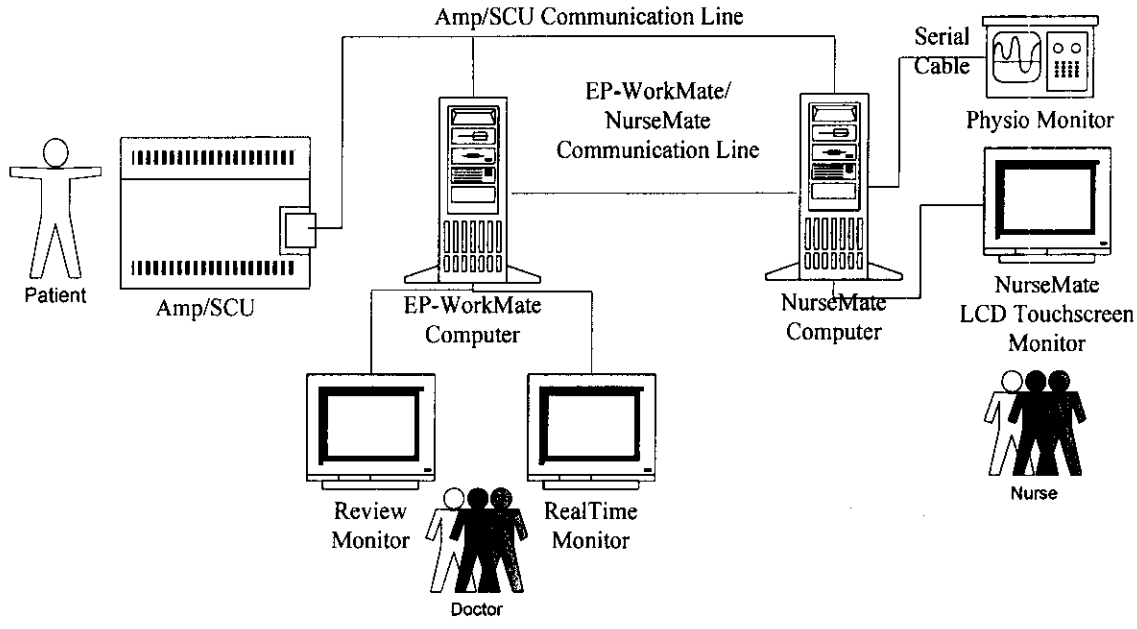

Figure 6: EP-WorkMate® with NurseMate™ with Physio Module Interconnection Diagram

7.8 **System Data Flow:**

7.8.1 Data is received by the NurseMate™ with Physio Module from the EP-WorkMate® via the two interconnections. The NurseMate™ with Physio Module user can view and edit clinical data from the EP-WorkMate® (e.g., intracardiac ECG waveforms) during the EP procedure. NurseMate™ with Physio Module users may independently enter tabular data regarding the case (e.g., event identification, medication, and nurses' or doctors' comments). NurseMate™ with Physio Module controls only start/stop recording in the EP-WorkMate®; it does not control any aspect of other devices interconnected with the EP-WorkMate®.

7.8.2 Data is received by the NurseMate™ with Physio Module for the OEM physiologic monitor by one interconnection. The NurseMate™ with Physio Module receives physiologic data from the OEM physiologic monitor for inclusion in the patient electronic charting log. Tabular data entries are stored as part of the patient file on the EP-WorkMate® as if the data were manually entered on the EP-WorkMate®. NurseMate™ with Physio Module does not control the OEM physiologic monitor in any way. NurseMate™ with Physio Module has no alarms or real time physiologic data display; these functions remain separately resident on the physiologic monitor.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2007

EP Medsystems
C/O Mr. Larry Picciano
Cooper Run Executive Park
575 Route 73 North, Bldg D
West Berlin, NJ 08091-9293

Re: K070706
Trade/Device Name: NurseMate with Physio Module
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: 13 Mar 2007
Received: 14 Mar 2007

Dear Mr. Picciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

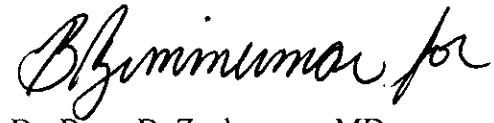
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Dr. Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EPMedSystems

Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, New Jersey 08091
Tel: (856)753-8533
Fax: (856)753-8544

Indications for Use

Device Name: NurseMate™ with Physio Module

Indications for Use: NurseMate™ with Physio Module is indicated for use during clinical electrophysiology procedures.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070706